

Reference No.: DVB/2024-25/049

Date: 30-09-2024

To,
The Environmental Engineer,
Regional Office-I
T. S. Pollution Control Board,
H. No. 6-3-1219, Street No. : 1
Block C Ward 91, ^{gnd} First Floor,
Uma Nagar, Begumpet, Hyderabad -Telangana

Subject: Submission of Environmental Statement (Form V) for 2023-2024- Reg.

Ref: CFO Order No. 7-RR-I/TSPCB/ZOH/TS-iPASS/CFO/2021-29 Dated: 16-04-2021

Sir,

We are pleased to submit herewith 3 copies of Environmental Statement (Form V) for the financial year 2023-2024 for our unit located at Plot No. 575, Sivareddyguda, Ghatkesar, Medchal district, Hyderabad, Telangana.

Kindly acknowledge the same.

Thanking You,

Yours Faithfully,

For M/S Dano Vaccines & Biologicals Pvt. Ltd.

D. Suryanarayana

Authorized Signatory

Encl: As above



DANO VACCINES & BIOLOGICALS PRIVATE LIMITED

Regd. Off : H.No. 2-2-647/771A/1, Srinivasa Nagar Colony, Bagh Amberpet, Hyderabad - 500 013. (T.S.)

Factory : 575, Sivareddyguda, Ghatkesar - 501 301. (T.S.)

Ph : +91-40-27421435, +91-94400 66435, E-mail : info@danovaccines.com / www.danovaccines.com

CIN : U24231TG1984PTC005135

PAN : AABCD0349R

GSTIN : 36AABCD0349R12C



AN ISO 9001:2015 CERTIFIED COMPANY

**ENVIRONMENTAL AUDIT REPORT
(FORM – V)**

OF

**M/s. DANO VACCINES & BIOLOGICALS (P) LTD.
575, SHIVAREDDYGUDA
GHATKESAR MANDAL
MEDCHAL DISTRICT
TELANGANA STATE**

FOR THE

FINANCIAL YEAR ENDING

31ST MARCH 2024

(FORM – V)

**ENVIRONMENTAL STATEMENT OF M/s. DANO VACCINES & BIOLOGICALS PVT.LTD.,
575, SHIVAREDDYGUDA, GHATKESAR MANDAL, MEDCHAL DISTRICT, TELANGANA
FOR THE FINANCIAL YEAR ENDING MARCH- 2024**

Introduction:

Environmental Statement/Environmental Audit Report is a report that provides the complete scenario of the Environment Quality in and around the industry in operation. A gazette notification on Environmental Statement / Environmental Audit was brought out by the Ministry of Environment & Forests on 13th March 1992 and amended vide notification G.S.R. 386 (E) dated 28th April, 1993 under which every person seeking consents under Sec. 25 of the Water (Prevention and Control of Pollution) Act 1974 or under Sec. 21 of the Air (Prevention and Control of Pollution) act 1981, or Both or Authorization under the Hazardous Wastes (Management and Handling) Rules, 1989, issued under the Environment (Protection) Act 1986 shall submit an environmental statement for the year ending 31st March in Form - V to the concerned State Pollution Control Board on or before 30th day of September every year.

Definition of Environmental Audit:

The International Chamber of Commerce defines Environmental Audit as a Management Tool comprising of a Systematic, Documented, Periodic and Objective Evaluation of how well environmental organization, management and equipment are performing with the aim to regulate the environmental policy by:

1. Facilitating management control of environmental practices, and
2. Assessing compliance with company policies, which would include meeting regulatory requirement.

As a management tool, environmental audit would allow the management to look inwards and see as to whether cleaner technologies could be adopted which would avoid generation of wastes. The audit strikes a balance between the industrial unit and regulatory bodies by resolving the conflicts of their interests by assisting the industrial units to attain compliance with the prescribed standards and improve productivity. Preparation of such audits also help to bridge the gap by assuring optimum protection of environment and minimizing the insurance liability by better environmental management. There is hardly any management goal that is not served by environmental audit from prevention of waste and excessive consumption of resources, creation of an environment conducive to efficiency and optimum productivity and a harmonious relationship with common public and regulatory authority. Thus, environmental audit can help improve corporate environmental performance and also provide basis for reporting this performance to company stake holders.

Dano Environmental Statement

M/s. Dano Vaccines & Biologicals Pvt. Ltd., being conscious of its responsibilities towards Protection of Environment by minimizing the pollution load due to the project activities has undertaken preparation of Environmental Statement / Audit Report for their unit for the Financial year ending 31st March 2024.

THE COMPANY:

M/s. Dano Vaccines & Biologicals Pvt. Ltd. is in the line of manufacturing Tetanus Toxoid (Adsorbed) I.P., which is the only preventive medicine available for protecting the human beings from Tetanus infections. The unit is located on a 2.29 acre plot bearing plot No. 575, in Sivareddyguda, within the periphery of Ghatkesar Mandal of Medchal Dist, falling on the Hyderabad - Warangal State Highway at a distance of about 22Kms from the city of Hyderabad. The industry is in operation since 1985 onwards. The manufacturing of the Vaccine is based on the toxoid processed from *Clostridium tetani*, which is considered to be a hazardous microorganism and is categorized under risk group III under the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms / Genetically Engineered Organisms or Cells, 1989.

OBJECTIVES OF THE PROJECT:

- To make available the product at a very reasonable cost compared to imported product.
- To make available the product easily to the other units who develop this product for consumption by the end user.
- To adopt the best technology available for such product manufacturing.
- To make use of the resources available and thus strengthen the economy.
- To utilize the services of the local people and improve their standard of living.
- To manufacture the products under Environment friendly conditions there by protecting the Environment

LOCATION

The site has been selected on the basis of scientific evaluation of various environmental, production, financial and other aspects. The plant is located in a 2.29 acre plot at Shivareddyguda, Ghatkesar, Ghatkesar Mandal, Medchal District of Telangana at a distance of 22Kms from the City of Hyderabad on Hyderabad – Warangal State Highway.

The industry has been regularly applying for and obtaining the Consent for Operation under Air Act and under Water Acts respectively.

INDUSTRY AND ENVIRONMENT:

M/s. Dano Vaccines & Biologicals Pvt. Ltd., manufactures Tetanus Toxoid (Adsorbed) I.P using *Clostridium tetani* as the production system apart from chemicals like peptone, Sodium chloride etc., as raw materials. The handling and processing of *Clostridium tetani* and other chemicals carry limited risks to the people working on it and also to the environment, provided necessary precautions are taken while handling them. M/s. Dano Vaccines & Biologicals Pvt. Ltd., is conscious of its responsibilities towards the Environment and the Society in minimizing the pollution load due to the project activities and is following Good Laboratory Practices (GLP). It is also adhering to stringent environmental management practices. The industry has also applied for Environmental Approval to the Genetic Engineering Approval Committee (GEAC) under Ministry of Environment and Forests, New Delhi. An Environmental Clearance was accorded by GEAC, based on the application made by the industry. It has prepared an On-Site Emergency Plan for which the studies were carried out. The industry has also constituted an Institutional Bio-Safety Committee (IBSC) involving experts from different fields, including a main nominee from Department of Biotechnology, and has already conducted the meeting regularly twice a year. It is implementing all the suggestions put forth by the IBSC.

The industry has taken all necessary precautions to combat the above polluting factors. Air Pollution caused by the oil fired boiler is quite negligible as the boiler is operated only for a maximum of 6-7 hours per day as the industry operations are limited only to a single shift; Autoclaving the contaminated equipment, materials and killing the live organisms if any, by heat treatment for control of Water Pollution. The effluents generated are decontaminated and after treating in the ETP, it is used for the development of the Greenbelt inside the plant premises. The industry also intends to monitor regularly the pollution generated in Air and Water by appointing Consultants.

The solid waste in the form of broken / rejected ampoules and vials are discarded and disposed off as scrap. Other solid waste from the animal section is being disposed to third party biomedical waste service providers M/s Sattva Global Services Pvt. Ltd.

The industry has been exempted from obtaining GEAC Approval by Genetic Engineering Approval Committee vide Lr. No. 13/4/99-HSMD dated 3rd May 2000. However it is regularly conducting Institutional Bio-Safety Committee (IBSC) Meetings and is complying with the directions of the Committee.

The Environmental Statement in Form – V shows the Water Requirement, Water consumption for manufacturing one Single Dose, Raw Material Consumption for manufacturing the product, Quantity of Pollution generated in Air and Water, its control and discharge, Generation of Hazardous Waste and its Quantity, Quantity of Solid Waste Generated on daily basis, its treatment / disposal, Green Belt Development,

Dano Environmental Statement

Re-use / Recycling of the Waste water generated etc. The statement also provides the measures the industry proposes to adopt in controlling / abetting the pollutants generated from the project site, etc.

(FORM – V)

**ENVIRONMENTAL STATEMENT OF M/s. DANO VACCINES & BIOLOGICALS PVT. LTD., 575,
SHIVAREDDYGUDA, GHATKESAR MANDAL, MEDCHAL DIST, TELANGANA
FOR THE FINANCIAL YEAR ENDING MARCH- 2024**

PART – A

i) Name and address of the Owner / Occupier of the Industry in Operation/
Manufacturing Process : Mr.D.Suryanarayana Raju M. D.
M/s. Dano Vaccines & Biologicals Pvt. Ltd.,
575, Sivareddyguda, Ghatkesar Mandal
Medchal District, Telangana.

ii) Date of the Last Environmental Audit Report Prepared / Submitted : September 2023

iii) Production Capacity – Units :

Products:

1. Tetanus Toxoid (Adsorbed) I.P : 6000Ltrs / Month

Formulations:

2. Gentamicin Injection I.P : 125Ltrs / Month
3. Norfloxacin Eye Drops : 100Ltrs/Month
4. Gentamicin Eye Drops : 200Ltrs/Month
5. Ciprofloxacin Eye Drops : 200Ltrs/Month
6. Ranitidine HCl Injections : 100Ltrs/Month
7. Dexamethasone Injections : 100Ltrs/Month
8. Diclofenate Sodium Injections : 200Ltrs/Month
9. Amikasin Injections (100mg) : 20Ltrs/Month
10. Frusemide Injections : 20Ltrs/Month

iv) Year of Establishment : 1985

CFO Order No.

7-RR-I/TSPCB/ZOH/T-iPASS/CFO/2021-29 dated 16.04.2021 Valid up to 31-12-2025

PART – B

WATER AND RAW MATERIAL CONSUMPTION

i) Water Consumption:

a) Process	:	6.0 KLD
b) Washing	:	8.0 KLD
c) Boiler feed	:	21.0 KLD
d) Cooling make up	:	25.0 KLD
e) Canteen	:	6.0 KLD
f) Domestic	:	6.0 KLD
g) Domestic from quarters	:	20.0 KLD
Total	:	92.0 KLD

Name of the Products	Process water consumption per unit of Product (Ltrs / Kg. of product)	
	During the Previous Financial Year (2022-2023)	During the Current Financial Year (2023 - 2024)
1. Tetanus Toxoid (Adsorbed) I.P.	69600 Ltrs	53200 Ltrs
2. Formulations Products from item No. 2 to 10 of CFO Products	Nil	Nil

ii) Raw Material Consumption:

Name of the Raw Materials	Name of the Products	Consumption of Raw Materials per unit of Product (Kgs / Kg of product)	
		During the Previous Financial Year (2022-2023)	During the Current Financial Year (2023 - 2024)
1. *Listed in Annexure II	Tetanus Toxoid Adsorbed I.P	69600 Ltrs	53200 Ltrs
2. Formulations Products from item No. 2 to 10 of CFO Products		Nil	Nil

*Raw Materials Listed in Annexure – I.

PART – C

POLLUTION GENERATED

(Parameter as specified in the consent issued)
Pollutants discharged to environment per unit of output

Pollutants	Quantity of Pollutants Discharged (kg/day)	Concentration of Pollutants discharged (mg/l)*	Percentage of Variation from prescribed standards with reasons
a) Water i) from process, Cooling, Boiler & washings	TDS - 3.66 TSS - 0.11 COD - 0.51 BOD - 0.09 Chlorides – 0.83 Sulfates –1.16 Oil & Grease –BDL pH - 7.38	TDS - 804.75 TSS - 25.66 COD - 112.46 BOD - 20.00 Chlorides –183.33 Sulfates – 256.166 Oil & Grease – BDL pH - 7.38	61.7% less than the standards 87.2% less than the standards Not Specified 33.3% less than the standards Not Specified Not Specified 100% less than the standards 18%less than the standards
Boiler Stack	PM – 0.136 Kg/hr SO ₂ – 0.36 Kg/hr NO _x – 0.44 Kg/hr	PM – 55.83 mg/Nm ³ SO ₂ - 149.58 mg/Nm ³ NO _x - 180.0 mg/Nm ³	51.4% Less than the standards 75.1% Less than the standards 70% Less than the standards

*Effluent and Stack Analysis Reports for the month of March 2024 are enclosed

** Effluent treated in the ETP. The characteristics are well within the limits prescribed by the Board in its Consent Order.

PART – D

(HAZARDOUS WASTES)

(As specified under Hazardous Wastes (Management and Handling) Rules, 1989)

Total Quantity (Tons.)

Hazardous Waste	During the Previous Financial Year (2022-2023)	During the Current Financial Year (2023- 2024)
Waste Oil	73 Ltrs	38Ltrs
ETP Sludge	57 Kgs	54 Kgs

PART – E

(SOLID WASTES)

Total Quantity (Tons / Year)

	During the Previous Financial Year (2022-2023)	During the Current Financial Year (2023 - 2024)
1. From Process Productionof BPTT (API) (BMW)	1.66 Tons	0.6 Tons
2. From Formulationof Ampoules & Vials, QC &Other Sections (BMW)	31.42 Tons	12.5 Tons

PART – F

Please specify the characteristics (in terms of concentration and quantum) of Hazardous as well as solid wastes and indicate disposal practice adopted for both these categories of Wastes.

There is no Hazardous waste generated in the plant except the waste oil from D.G. sets.

The solid organic waste (BMW) from Production of BPTT (API) generated is about 0.6 Tons
The total quantity of Solid Waste (BMW) generated is about 12.5 tons is in the form of broken and rejected ampoules and vials, Gloves, Face masks, shoecovers and head caps are disposed off as waste (sent to 3rd party vendor - SATTVA ENVIRO)

PART – G

Impact of the pollution control measures on conservation of natural resources and consequently on the cost of production.

Adequate measures are taken to maintain minimum levels of pollution in and around the plant premises. There is minimum impact on the surrounding environment.

The industry is operating a full-fledge effluent treatment plant to treat the effluents coming from process, washing, DM Plant up to the standards prescribed by the TGPCB. The treated effluent is used for the development of greenbelt.

The industry has contract agreement with 3rd party vendor - SATTVA ENVIRO for incinerating the Experimented animals, disposing off the Solid waste (Fibrous mass, and other organic matter) generated in the process

PART – H

Additional Investment proposal for environmental protection including abatement of pollution:

The industry has contract agreement with 3rd party vendor - SATTVA ENVIRO for disposing off the BMW waste generated in the process and Experimented animals.

The industry has also constructed a full-fledged Effluent Treatment Plant for treating the effluents generated from the process using a diffused Aeration system.

PART – I

Any other particulars in respect of environment protection and abatement of pollution.

The industry has already grown plenty of trees consisting of teak, neem, flowering trees etc., in its premises and has maintained a beautiful lawn with different varieties of plants / Shrubs etc. It is following good housekeeping practices that helps in clean environment for the production activities. Contaminated articles etc., are carefully handled by the experienced and trained staff and above all the Management is very particular in following the Cleaner Technology Practice.

LIST OF ANNEXURES ENCLOSED

1. RAW MATERIAL CONSUMPTION PER UNIT OF PRODUCT
2. MANUFACTURING PROCESS DESCRIPTION AND FLOW CHART
3. MONTHWISE PRODUCTION DETAILS
4. CONSENT FOR OPERATION COPY
5. MONTHWISE WASTE OIL DISPOSAL DETAILS AND SOLID WASTE DISPOSAL DETAILS
6. MONTHWISE WATER CONSUMPTION AND WASTE WATER GENERATION DETAILS
7. MONTHWISE DIESEL & ENERGY CONSUMPTION
8. AMBIENT AIR QUALITY REPORT
9. WASTE WATER ANALYSIS REPORT
10. NOISE LEVELS REPORT
11. COMPLIANCE REPORT OF CONDITIONS STIPULATED IN SCHEDULE –A, SCHEDULE – B & SCHEDULE – C OF CONSENT ORDER

ANNEXURE-I

**List of Raw materials used for the manufacturing of
Tetanus Toxoid (Absorbed) I.P.**

Sl. No.	Description	Unit	Raw material Qty./ Litre of product
1.	Glucose	Kg	0.0125
2.	Sodium Chloride	Kg	0.0029
3	Disodium Hydrogen Orthophosphate	Kg	0.0011
4	Potassium Phosphate	Grams	0.1711
5	Magnesium Sulphate	Grams	0.1711
6	L.Cystine	Kg	0.0003
7	Uracil	Grams	0.0033
8	L. Tyrosine	Kg	0.0006
9	Calcium D- Pantothenate	Grams	0.0013
10	Thiamine	Grams	0.0003
11	Pyridoxine	Grams	0.0003
12	Riboflavine	Grams	0.0003
13	Biotin	mg	0.0003
14	Sodium Hydroxide	Kg	0.0081
15	Beef	Kg	0.1304
16	Papain	Kg	0.0008
17	Ferrous Sulphate	Grams	0.0456
18	Acetic Acid	Ltr	0.0041
19	Conc. Hcl.	Ltr	0.0033
20	Formaline	Ltr	0.0065
21	Toluene	Ltr	0.0005
22	Ammonium Sulphate	Kg	0.0125
23	Aluminium Chloride	Kg	0.0026
24	Thisodium orthophosphate	Kg	0.0070
25	Disodium hydrogen orthophosphate	Kg	0.0004
26	Sodium Chloride	Kg	0.0040
27	Thiomersal	Grams	0.1316

ANNEXURE – II

**MANUFACTURING PROCESS AND PROCESS FLOW CHART OF
TETANUS TOXOID ADSORBED (I.P.)**

Tetanus is mainly a disease of wounds. The causative organism is *Clostridium tetani*. A characteristic feature of these bacteria is the formation of endospores, at one end of the cell, giving the organism a drum-stick appearance. The organism occurs in the intestinal tract of herbivorous animals and is widely distributed in the soil. In humans, deep and ragged wounds with devitalised tissue provide favourable conditions for the growth of these organisms. The organism has very little invasive capacity but produces a powerful neuro toxin, which is entirely responsible for all the harmful effects of the disease. Symptoms include violent contraction of the muscles, usually of the neck and jaw restricting opening of the mouth, which is called as lockjaw. Natural disease of tetanus does not confer immunity because a lethal dose of toxin is too small an amount of antigen that is required to give rise to immunity. A very high mortality rate still exists and tetanus and tetanus neonatorum still is a worldwide problem.

But the disease is entirely preventable by active immunization using vaccine. Vaccine is a preparation of killed or attenuated microorganisms or their components or their products which is used to induce active immunity against the disease. The fact that tetanus organisms produce a toxin is made use for the manufacture of vaccine. The toxin that is converted to harmless toxoid becomes a most potent antigen. This characteristic feature is utilized for preventing the disease by making good vaccine available.

Manufacturing Process of Tetanus Toxoid (Adsorbed) I.P.:

The non-sporing Harvard Strain (No. 49205) obtained from Central Research Institute, Kasauli is used as the seed material for the manufacture. The strain is maintained by selective sub-culture in alternate thioglycollate medium and Heart Infusion Glucose Broth (HIGB).

The material from the Liquid culture is transferred aseptically into alternate thioglycollate medium and incubated at $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ for 48 hrs. This culture is transferred to required number of tubes containing Heart Infusion Glucose Broth (HIGB). The balance material is stored at $+4^{\circ}\text{C}$. The HIGB tubes are also incubated at $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ and subcultures are prepared every 24hrs using the same medium. The earlier subcultures are stored at $+4^{\circ}\text{C}$ for further use. The volume and the number of subcultures depend on the production

requirement. For subcultures anaerobic condition is maintained by layering the medium with sterile liquid paraffin.

For production – a suitable medium with sources of carbon, nitrogen mineral salts and a few essential amino acids and vitamins is prepared. Papain digest broth is used as the basic component in the medium. The completed medium with a pH of 7.5 is sterilized in S.S. cans, each with 25 liters of medium and sterilized at $118^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ for 20 minutes. After sterilization, the medium is rapidly cooled to 35°C in running cold water. The inoculation with 24hrs old culture is done aseptically and the containers are incubated at $35^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ for a period of 7 days.

After 7 days, a sample is taken from each S.S Jar and centrifuged. The bacterial purity is checked by examining the smears for each container. Only containers that do not show any microbial contamination are taken for harvesting. The supernatant fluid from these containers is pooled and tested for antigen content as Lf units/ml.

Harvesting is by pooling the culture from all the Jars and removing the residual bacterial mass. This is done by micro flow filtration using 0.2μ cartridge filter and collected in sterile containers. A sample of the filtered toxin is taken for checking the Lf/ml, MTV & MLD. Formalin is added at 0.5% level and the toxin containers are shifted to $36^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ and incubated for a period of 4 weeks for detoxification, to convert the toxin to toxoid.

At the end of this period, a sample is taken from each container and checked for completed detoxification by inoculating into mice. 1ml of toxoid is inoculated into each animal subcutaneously and observed for 10 days. The inoculated animal should not show any symptoms and should survive the test period. Only after successful completion of this test the material is taken for further concentration and purification.

Usually 3000 to 3200 liters of crude toxoid is processed as one pool. As a first step of purification, the crude toxoid is concentrated. Tangential flow filtration (TFF) technology is applied using membranes that have a molecular cut off at 10,000 level. 800 – 1000 liters of crude toxoid can be conveniently concentrated to 5 liters in one working day. The concentrated toxoid is pooled and the antigen content (Lf/ml) is estimated to check the recovery.

The concentrated toxoid is purified by fractional precipitation using Ammonium sulphate. The purification is done mainly to eliminate any allergic / low molecular substances in the toxoid and to increase the immunogenicity of the toxoid. A preliminary testing is done to choose the two salt concentrations required for purification. Usually, the first precipitation is done at 11% followed by the second at 24%. For the concentrated toxoid, the pH is adjusted to 7.4 using ammonia solution and then the required amount of salt for a 11% concentration is added, mixed well and left at room temperature overnight.

The Tetanus Toxoid is centrifuged at 4000 ± 100 rpm for 30 minutes by refrigerated centrifuge (temperature between $2-8^{\circ}\text{C}$) using polypropylene containers. After the process collect the Toxoid's Supernatant and adjust the pH to 7.8 – 8.0 using liquid Ammonia solution, then ammonium sulphate salt concentration is increased to 24% and kept at room temperature for overnight proper mixing. Next day the toxoid is centrifuged at 4000 ± 100 rpm for 45 minutes by refrigerated (temperature between $2-8^{\circ}\text{C}$) using polypropylene containers. After the process, the whole precipitate is carefully removed from each container using normal saline and subject to diafiltration using tangential flow filtration technology to remove the Ammonium sulphate salt from the Tetanus Toxoid. Once the diafiltration is completed, the fluid material, which represents the concentrated and purified tetanus toxoid, is carefully collected in sterile bottles. Since, the concentration and purification are non-sterile procedures, toluene is added to the toxoid to prevent any contamination. The toxoid thus purified is sterilized by filtration through $0.45\mu\text{m}$ & $0.2\mu\text{m}$ cartridge. After sterile filtration, thiomersal is added at 0.02% (1/5000) level as the preservative.

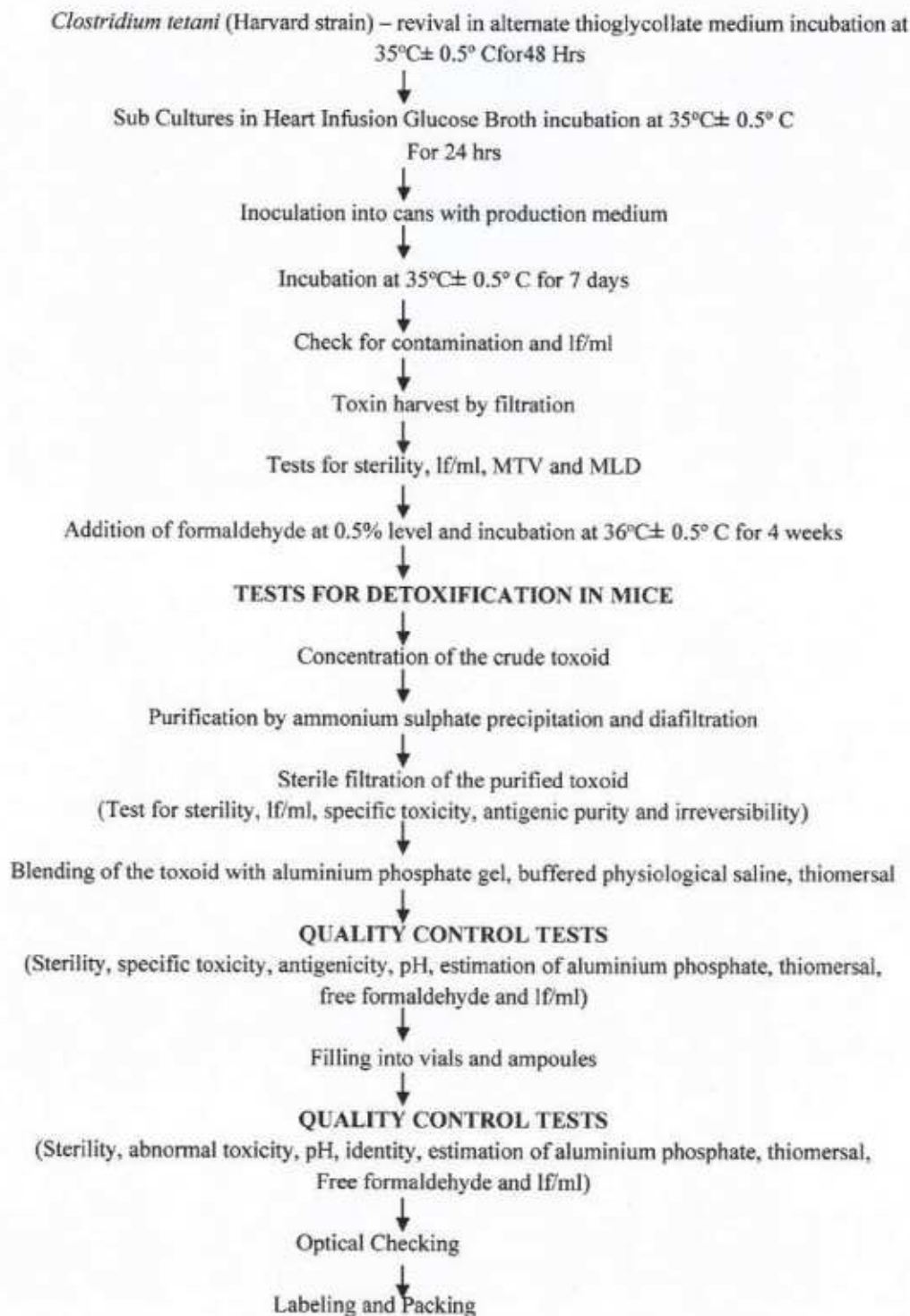
The purified toxoid is checked for lf/ml sterility, specific toxicity, irreversibility and antigenic purity.

The aluminium phosphate gel is used as the adjuvant for the adsorption of tetanus toxoid. The gel is prepared by mixing aluminium chloride solution and tri-sodium orthophosphate solution. The gel also contains thiomersal as the preservative. After checking the sterility of the gel, it is diluted with the required volume of saline. The purified toxoid is added to the gel so as to have 14Lf/ml of the final formulation.

The composition of the final vaccine is as follows:

Tetanus Toxoid 14Lf/ml. Aluminium phosphate gel is 3 mg/ml. The preservative, thiomersal is in 0.01% (1/10,000) level. After blending, the final vaccine is collected in 20 liter bottles. A representative sample is collected for performing the tests as required by L.P. 2018. The bulk is taken for filling after it passes all the tests. The filling is carried out as per the requirements, either as single dose ampoules or as multi dose vials.


FLOW CHART



ANNEXURE - III

**MONTHWISE
PRODUCTION DETAILS**
During the year April 2023- March 2024

Name of the Intermediate	Apr' 23	May' 23	Jun' 23	Jul' 23	Aug' 23	Sep' 23	Oct' 23	Nov' 23	Dec' 23	Jan' 24	Feb' 24	Mar' 24
	Ltrs											
Tetanus Vaccine (Adsorbed) I.P	6000	6000	4400	4800	6000	6000	6000	3600	6000	4400	NIL	NIL
Gentamycin Injection I.P	-	-	-	-	-	-	-	-	-	-	-	-
Norfloxacin Eye Drops	-	-	-	-	-	-	-	-	-	-	-	-
Gentamycin Eye Drops	-	-	-	-	-	-	-	-	-	-	-	-
Ciprofloxacin Eye/Ear Drops	-	-	-	-	-	-	-	-	-	-	-	-
Ranitidine HCl Injection I.P	-	-	-	-	-	-	-	-	-	-	-	-
Dexamethasone Injection	-	-	-	-	-	-	-	-	-	-	-	-
Diclofenate Sodium Injection	-	-	-	-	-	-	-	-	-	-	-	-
Amikasin Injection	-	-	-	-	-	-	-	-	-	-	-	-
Frusemide Injection	-	-	-	-	-	-	-	-	-	-	-	-



TELANGANA STATE POLLUTION CONTROL BOARD
ZONAL OFFICE: HYDERABAD

D. Krananand
Joint Chief Environmental Engineer

DESPATCHED
ON 16/04/2021

H.No.6-3-1210, Sy.No.TS No.1 Part,
Block - C, Ward No.91, Near Country Club,
Uma Nagar, Begumpet, Hyderabad
Phone: 040-23402405
Email: jce-zhyd-tspcb@telangana.gov.in

CONSENT & AUTHORIZATION ORDER - RED CATEGORY

Consent Order No: 7-RR-1/TSPCB/ZOH/TS-IPASS/CTO/2021- 29 Date: 16.04.2021

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/effluent under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof and Operation of the plant under section 21 of Air (Prevention & Control of Pollution) Act, 1981 and amendments thereof) and Authorization / Renewal of Authorization under Rule 6 of the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016.

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21 of Air (Prevention & Control of Pollution) Act, 1981 (hereinafter referred to as 'the Acts') and Authorization under the provisions of HW (M & TM) Rules, 2016 (herein after referred to as 'the Acts' 'the Rules') the rules and orders made thereunder to

M/s. Dano Vaccines & Biologicals Pvt. Ltd.,
575, Sivareddyguda, Ghatkesar,
Medchal - Malkajgiri District

(hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant, to discharge the effluents from the outlets and the quantity of Emissions per hour from the chimneys as detailed below.

i) Outlets for discharge of effluents:

Outlet No.	Outlet Description	Max Daily Discharge	Point of Disposal	Limiting Standards
1	Process, Washings & Boiler Blow Down	5.5 KLD	After treatment in the ETP, the treated waste shall be used for on land for gardening within the industry premises, duly meeting the irrigation standards stipulated.	pH - 5.5-9.0; Total Suspended Solids - 200.0 mg/l; Oil & Grease - 10.0 mg/l; Biochemical Oxygen Demand (3 days at 27°C) - 30.0 mg/l
2	Domestic effluents	1.0 KLD	Septic tank followed by soak pit.	---

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow	Emission Standards
1.	Attached to the HSD fired boiler of capacity - 0.6 TPH	---	SPM - 115 mg/Nm ³
2.	Attached to Diesel fired incinerator of capacity 2 Kgs/Hr.	---	SO ₂ - 600 mg/Nm ³ At 6% dry O ₂ for solid fuel and 3% dry O ₂ for liquid fuel NOx - 600 mg/Nm ³ At 6% dry O ₂ for solid fuel and 3% dry O ₂ for liquid fuel
3.	Attached to the DG Set of capacity - 300 KVA	---	SPM - 115 mg/Nm ³

4.	Attached to the DG Set of capacity - 125 KVA	SPM - 115 mg/Nm ³
----	--	------------------------------

iii) Hazardous Waste Authorization: (Form - 2) [See Rule 6(3)]:

M/s. Dano Vaccines & Biologicals Pvt. Ltd., 575, Sivareddyguda, Ghatkesar, Rangareddy District is hereby granted an authorization to operate a facility for collection, reception, storage, transport and disposal of the following wastes with quantities as mentioned below:

S. No.	Name and quantity of the Hazardous waste	Stream	Disposal option
1.	Waste Oil (300 LPA)	3.1 of Sch - I	Shall be sent to authorized waste oil Re-Processors / Re-Cycling units.
2.	ITP Sludge (20 Kgs/month)	3.4.3 of Sch-I	Shall be lifted to M/s. HWMP (ISDF), Dumlajal, Medchal-Malkajgiri District.

This order is subject to the provisions of 'the Acts' and 'the Rules' and orders made thereunder and further subject to the norms and conditions incorporated in the schedule A, B and C enclosed to this order.

This consent is valid for manufacture the following products along with quantities only

S.No.	Product & By product	Total Capacity
01.	Anakasin Injection	20 Ltrs/month
02.	Ciprofloxacin Eye / Ear Drops	200 Ltrs/month
03.	Dexamethasone Injection	100 Ltrs/month
04.	Diclofenate Sodium Injection	200 Ltrs/month
05.	Frasamide Injection	20 Ltrs/month
06.	Gentamycin eye drops	200 Ltrs/month
07.	Gentamycin Injection I.P.	125 Ltrs/month
08.	Norfloxacin Eye Drops	100 Ltrs/month
09.	Ranidine HCl Injection LP.	100 Ltrs/month
10.	Tetanus Tokoid (Absorbed) LP.	6000 Ltrs/month

This combined order of Consent & Hazardous Waste Authorization shall be valid for a period ending with the 31.12.2025

JOINT CHIEF ENVIRONMENTAL ENGINEER

Encl: Schedules A, B & C

To
M/s. Dano Vaccines & Biologicals Pvt. Ltd.,
575, Sivareddyguda, Ghatkesar,
Medchal - Malkajgiri District.
E-mail Id: info@dano Vaccines.com

Copy to the Member Secretary, TSPCB, Board Office, Hyderabad for information
Copy to the General Manager, District Industries Centre, Near ORR, Keerasa, Medchal-Malkajgiri District, Collectorate Complex, Hyderabad - 500083.
Copy to the Environmental Engineer, TSPCB, Regional OfBce-I, Rangareddy District for information

SCHEDULE - A

1. The applicant shall make applications through online for renewal of consent (under Water and Air Acts) and Authorization under HWM Rules atleast 120 days before the date of expiry of this order, along with prescribed fee under Water and Air Acts for obtaining consent of the Board along with detailed compliance to the conditions stipulated in the CFO.
2. The industry shall immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions etc.
3. a) All the fugitive emissions shall be controlled with proper measures.
b) The applicant shall also install the equipment such as wind speed recorder and wind direction recorder.
4. The applicant shall not change or alter either the quality or the quantity or the rate of the discharge or the route of discharge and shall not change or alter either the prescribed quality or the rate of emission without the previous written permission of the Board.
5. The applicant shall, not later than 30 days from the date of issue of this consent order, certify in writing to the Board that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent. In absence of alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production shall be stopped.
6. Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and/ or violation of standards stipulated in this order or the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident, or other unforeseen act or event, the person-in-charge of the premises, from where such discharge / emission occurs or is apprehended to occur shall forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax / email under intimation to the Collector and District Magistrate.
7. In case of such episodal discharges / emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge / emission below the limits prescribed in this order.
8. A good house keeping shall be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers and drains shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way into storm drains or open areas.
9. a) The industry shall carryout analysis of waste water discharges or emissions through chimneys, for the parameters mentioned in Schedule - B of this order at regular intervals.
b) The industry shall maintain following records to accessible to the Board, whenever required.
 1. Analysis reports of waste water/ emissions.
 2. Log book for operation of pollution control systems.
 3. Inspection book.
10. The applicant shall set up THREE Ambient Air Quality Monitoring Stations for continuous recording of relevant critical parameters mentioned in Schedule - B as per the CPCB guidelines and submit monthly reports.
11. Separate power connection with energy meter shall be provided for the Pollution Control Equipment and record of power consumption and chemicals consumption for the operation of pollution control equipment shall be maintained separately.
12. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E (P) Rules, 1986 & its amendments thereof.
13. The applicant shall comply with the directives/orders issued by the Board in this consent order and at all subsequent times without any negligence on his part. The applicant shall be liable for such legal action against him as per provisions of the Law/Act in case if non-compliance of any order/directive issued at any time and/or violation of the terms and conditions of this consent order.

14. The applicant shall furnish to the visiting officer and / or the Board any information regarding the construction, installation or operation of the effluent treatment systems/ air pollution control equipment and such other particulars as may be pertinent for preventing and controlling pollution.
15. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability.
16. All the rules & regulations notified by Ministry of Environment and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes shall be followed.
17. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 shall be followed.
18. The occupier shall educate the workers and nearby public of possible accidents and remedial measures.
19. For any accident or spillage of hazardous wastes causing damage to the Environment, the occupier or the transporter as the case shall be held responsible.
20. In case of closure of industry, the un-used/not consumed raw materials falling under the category of Hazardous Chemicals and mentioned in Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment Rules, 2003 shall be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident. In case the above hazardous chemicals have lost their properties originally acquired, then they shall be treated as Hazardous Waste and they should be disposed off only to the authorized agencies of TSPCB in a safe manner.
21. The occupier shall prepare / update an emergency preparedness plan for safe handling of hazardous waste from time to time and submit the same to TSPCB. Emergency preparedness plan must be implemented immediately whenever there is fire, explosion or release of hazardous waste or hazardous waste constituents, which could endanger to human health or environment.
22. Packaging, labeling and transportation of Hazardous Wastes shall be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling shall be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.
23. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter shall carry a Transport Emergency (TREM) card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.
24. Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes should be thoroughly detoxified before selling to agencies authorized by TSPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste Containers / container Liners should be maintained in the following way:
 - i. Number of containers received.
 - ii. Date and method of detoxification.
 - iii. Name of agencies to whom containers were sold with quantities.
 - iv. Transportation particulars.
25. No Hazardous Wastes shall be mixed with any other waste or shall be discharged to a common, other internal, external sewerage or other drainage system without prior approval of TSPCB.
26. If HDPE bags are used for storing Hazardous Wastes, it should be ensured that they are perfectly sealed mechanically or double hot sealed. If MS / HDPE bags or drums are used for Hazardous Wastes, these drums / bags should be ensured that they are perfectly sealed.
27. The person authorized shall not rent, lend, sell, transfer their industrial premises without obtaining prior permission of State Pollution Control Board.
28. Any Unauthorized change in personnel, equipment and working condition as mentioned in the application by the person authorized shall constitute a breach of this authorization.
29. The industry shall comply with the provisions of Batteries (Management and Handling) Rules, 2001.

30. The applicant shall put up two black boards of size 6 ft by 4 ft. at the main entrance to their plant. One board shall contain the specific CFE and CFO conditions, in sufficiently large font size so that it can be read easily from a distance of 10 ft to a normal eye, and other board shall carry, again in sufficiently large font size so as to be able to read from a distance of 10 ft, the latest Water, Air, Noise and solid waste monitoring data as well as the maximum vulnerable zone.
31. The applicant shall exhibit the Consent & HW Authorization order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.
32. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves to it the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and its amendments thereof and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and its amendments thereof to review any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
33. The authorization issued under Hazardous and other wastes (Management and Transboundary Movement) Rules, 2016, shall comply with the provision of the Environment (Protection) act, 1986.
34. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Telangana State Water rules, 1976 and Air Rules 1982, to such authority (herein after referred to as the Appellate Authority) constituted under Section 28 of the Water (prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

SCHEDULE - B

Special Conditions:

1. The industry shall take steps to reduce water consumption to the extent possible and consumption shall NOT exceed the quantities mentioned below:

Sl. No.	Purpose	Total Quantity (KLD)
1.	Process	6.0 KLD
2.	Washings	8.0 KLD
3.	Boiler feed	21.0 KLD
4.	Cooling make up	25.0 KLD
5.	Canteen	6.0 KLD
6.	Domestic	6.0 KLD
7.	Domestic from quarters	20.0 KLD
TOTAL		92.0 KLD

2. The industry shall remit water cess as per the assessment orders as and when issued by Board.
3. The emissions shall not contain constituents in excess of the prescribed limits mentioned below:

Chimney No.	Parameter	Emission Standards (mg/Nm ³)
1 to 4	SPM	115

4. The industry shall comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.
5. The industry should comply with the National ambient air quality standards as per MoEF, GoI notification dated. 18.11.2009 along the premises of the factory as prescribed below:

S. No.	Parameters	Standards in µg/m ³
1	Particulate Matter(PM ₁₀)	100
2	Particulate Matter (PM _{2.5})	60
3	SO ₂	80
4	NOx	80

Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)
Night time (10 PM to 6 AM) - 70 dB (A).

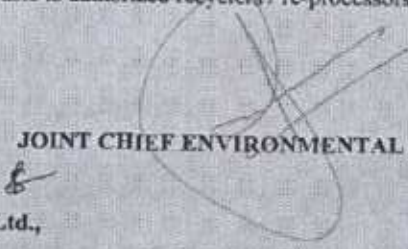
6. The industry shall manufacture only consented products and shall produce within the consented capacities. Under no circumstances, the industry shall manufacture any unconsented products without obtaining CPE & CFO of the Board.
7. The industry shall regularly operate effluent treatment plant (ETP) for effluents and after treatment, the treated wastewater shall be utilized for on land for gardening within the premises duly complying with the standards stipulated by the Board.
8. The industry shall provide suitable air pollution control equipment (APCE) to Diesel fired incinerator of capacity 2 Kgs/Hr and regularly operate the air pollution control equipment to meet the prescribed standards.
9. The industry shall install a separate energy meter for the effluent treatment plant (ETP) & APCE and maintain log registers to record the energy meter readings pertaining to the operation of the ETP and APCE.
10. The industry shall not discharge any wastewater outside the factory premises.
11. The industry shall not dispose any solid waste outside the premises.
12. The industry shall not cause any air pollution/dust nuisance to the surrounding environment.
13. The industry shall develop 33% of the total area as thick green belt all along the boundary of the unit and also in the vacant places with all tall growing trees with wide leaf area.
14. The industry should maintain the following records and the same should be made available to the Board Officials during the inspection.
 - a) Daily production details, RG-I records and Central Excise Returns.
 - b) Quantity of effluent generated, treated in ETP and utilized for gardening.
 - c) Log Books for pollution control systems.
 - d) Daily solid waste generated and disposed.
15. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
16. The following rules and regulations notified by the MoE&F, GoI shall be implemented.
 - a) Solid Waste Management Rules, 2016.
 - b) Construction and Demolition Waste Management Rules, 2016.
 - c) Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 & its amendments.
 - d) Batteries (Management & Handling) Amendment Rules, 2010 & its amendments.
 - e) E-Waste (Management) Rules, 2016.
 - f) Bio-Medical Waste Management Rules, 2016 & its amendments.
 - g) Plastic Waste Management Rules, 2016 & its amendments.
17. The industry shall take necessary measures to control fugitive emissions.
18. The industry shall take all precautionary and safety measures during process operations.
19. The industry shall comply with all the directions issued by the Board from time to time.
20. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control Acts.
21. The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.
22. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.

SCHEDULE - C
(See Rule 6(2))

(Conditions of Authorization for occupier or operator handling hazardous wastes)

1. The industry shall give top priority for waste minimization and cleaner production practices.

2. The industry shall not store hazardous waste for more than 90 days as per the Hazardous & other wastes (Management and Transboundary Movement) Rules, 2016.
3. The industry shall not sell the used empty drums / barrels / liners / bags / Bottle etc. to outside parties & vendors for reuse, instead they shall discard the same to avoid reuse, which is resorting in illegal dumping of Hazardous Waste and shall dispose the same directly to authorized recyclers only.
4. The industry shall ensure for proper labelling of Hazardous Waste / other waste containers with particulars of industry & type of Waste along with characteristics, while storage & transporting the waste to Recyclers / TSDF / Cement Industries.
5. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal.
6. The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors / Recyclers.
7. The industry shall dispose Used Lead Acid Batteries to the manufacturers / dealers on buyback basis.
8. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.
9. The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board Office and concerned Regional Office.
10. The industry shall maintain good housekeeping & maintain proper records for Hazardous Wastes stated in Authorisation.
11. The industry shall maintain proper records for Hazardous Wastes stated in Authorisation in FORM-3 and file annual returns in Form- 4 Rules 6(5), 13(8), 16(6) and 20(2) as per of the Hazardous & other wastes (Management, Transboundary Movement) Rules, 2016.
12. The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule B & C of this Order on half yearly basis to Board Office, Hyderabad and concerned Regional Office.
13. The industry shall dispose the e-waste to authorized recyclers / re-processors only.


JOINT CHIEF ENVIRONMENTAL ENGINEER

To
M/s. Dano Vaccines & Biologicals Pvt. Ltd.,
575, Sivareddyguda, Ghatkesar,
Medchal - Malkajgiri District.



**TELANGANA STATE POLLUTION CONTROL BOARD
REGIONAL OFFICE, RANGAREDDY DISTRICT**

H.No.6-3-1219, Block C, Ward No.91, 2nd Floor, Backside of Country Club, Kundanbagh, Umanagar, Begumpet, Hyderabad - 500016.

M. Venkat Narsu,
Environmental Engineer

Email: ee-rr1-tspcb@telangana.gov.in

AUTHORISATION

(Issued under Rule 10 of the Bio-Medical Waste Management Rules, 2016)

Order No.1489 / TSPCB/ RO-RRD/BMWA/2024- 2590

Date: 17.02.2024

1. M/s. Dano Vaccines & Biologicals Pvt Ltd., Sy. No. 575, Sivareddyguda, Ghatkesar, Medchal - Malkajgiri District is hereby granted an Authorization for Generation, segregation, Collection & Storage of Bio-Medical Waste.
2. M/s. Dano Vaccines & Biologicals Pvt Ltd., Sy. No. 575, Sivareddyguda, Ghatkesar, Medchal - Malkajgiri District is here by authorized for handling of biomedical waste as per the capacity given below:
 - i) Activity of HCF: Animal House for Vaccine Testing.
 - ii) Quantity of Biomedical waste handled, treated or disposed:

Type of Waste Category	Quantity permitted for Handling
Yellow (Dead Mices & Guinea Pigs)	350 Kgs/Month
Red (Plastic needles & Syringes)	50 Kgs/ Month
White (Translucent)	05 Kgs/ Month
Blue (Crushed Glass)	1000 Kgs/ Month

This authorization shall be in force for a period up to 31.12.2025.

- 3 This authorization is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.


ENVIRONMENTAL ENGINEER
ENVIRONMENTAL ENGINEER
Telangana State POLLUTION CONTROL
BOARD REGIONAL OFFICE - 1,
RANGAREDDY DISTRICT

N.B: This authorization shall be exhibited in the above premises and shall be produced from time to time at the request of the Inspecting Officer.

'CLEAN AND GREEN' TELANGANA

Terms and conditions of the authorizations:

1. **Non Bedded occupier shall dispose infectious liquid wastes only after treatment by disinfection as per Schedule-II(6) of the Principle Rule (BMW Management Rules).**
2. **The occupier shall provide CC Camera at waste storage area and pick up point of CBMWTF vehicle and the recorded data shall be stored for a period of 3 months and available for inspection by the Board Officials.**
3. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
4. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the Telangana State Pollution Control Board.
5. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the Telangana State Pollution Control Board.
6. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of this authorisation.
7. It is the duty of the authorised person to take prior permission of the Telangana State Pollution Control Board to close down the facility and such other terms and conditions that may be stipulated by the Telangana State Pollution Control Board.
8. Any other conditions for compliance as per the Guidelines issued by the MoEF & CC or CPCB from time to time.
9. The HCF shall upload the BM waste details in website
10. The HCF shall collect the mercury spillages and organic waste separately and dispose to the CBMWTF.
11. The Bio Medical Waste shall be disposed for treatment after disinfection and segregation to the following Common Bio-Medical Waste Treatment Facility.

**M/s Sattva Global Services Pvt Ltd., Plot No.
36/B, Biotech Park, Phase - III, Karakapatla
Village, Mulugu Mandal, Medak District**

SPECIAL CONDITIONS

1. All the provisions of the Bio-Medical Waste Management Rules, 2016 amendments thereof must be complied with.
2. The HCF shall take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with Bio-Medical Waste Management Rules, 2016 amendments thereof.
3. The HCF shall make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I of the BMW Rules, 2016. It shall be ensured that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I of the Bio-Medical Waste Management Rules, 2016.
4. The HCF shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDS Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal.
5. The HCF shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of the Bio-Medical Waste Management Rules, 2016.
6. The HCF shall dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time.
7. The HCF shall not to give treated bio-medical waste with municipal solid waste.
8. The HCF shall establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of the Bio-Medical Waste Management Rules, 2016.
9. The HCF shall ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities.
10. The HCF shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974).
11. The HCF shall maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I of the Bio-Medical Waste Management Rules, 2016.
12. The HCF shall inform to TSPCB immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time.

13. The HCF shall establish a system to review and monitor the activities related to bio-medical waste management by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority.
14. It is the responsibility of the occupier of the HCF that the only segregated bio-medical waste as per the Schedule – I of the BMW Management Rules, 2016 shall be handed over to common bio-medical waste treatment facility for treatment, processing and final disposal.
15. It shall be ensured that no untreated bio-medical waste shall be mixed with other wastes.
16. The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I of the BMW Management waste treatment Rules, 2016 prior to its storage, transportation, treatment and disposal.
17. The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV of the BMW Management Rules, 2016. The bar coding and global positioning system shall be added by the Occupier and Common bio-Medical Waste treatment facility in one year time.
18. Un-treated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not be kept stored beyond a period of 48 hours. Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority (TSPCB) along with the reasons for doing so.
19. Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
20. Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis is at temperature >1200C
21. Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
22. On-site pre-treatment of laboratory waste, microbiological waste, blood samples and blood bags should be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.

23. Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage.
24. The HCF shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste.
25. The HCF shall submit an annual report to the prescribed authority (TSPCB) in Form – IV, on or before the 30th June of every year for the period from January to December of the preceding year.
26. The HCF shall make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of the Bio-Medical Waste Management Rules, 2016.
27. In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator of HCF shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of Authorisation.
28. In case of any major accident at HCF facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.
29. The HCF shall ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments.
30. The occupier of the HCF or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio-medical wastes. The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.
31. The HCF shall adopt the following treatment and disposal methods as described in the Bio-Medical Waste Management Rules, 2016.
 - i. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate $\text{Log}_{10}4$ reduction efficiency for microorganisms as given in Schedule- III.
 - ii. Mutilation or shredding must be to an extent to prevent unauthorized reuse.
32. The HCF shall provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report.

33. The facility shall immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time.
34. The facility shall conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same.

To
M/s. Dano Vaccines & Biologicals Pvt Ltd.,
Sy. No. 575, Sivareddyguda, Ghatkesar,
Medchal - Malkajgiri District


ENVIRONMENTAL ENGINEER
ENVIRONMENTAL ENGINEER
Telangana State POLLUTION CONTROL
BOARD REGIONAL OFFICE - 1,
RANGA REDDY DISTRICT.

This authorization shall be exhibited in the above premises and should be produced from time to time at the request of the Inspecting Officer.

Annexure-V

**MONTH WISE WASTE OIL DISPOSAL DETAILS
AND SOLID WASTE GENERATION DETAILS**

During the year April 2023 – March 2024

Month	Waste Oils & Grease	ETP Sludge
	In liters	In kgs
April 2023		5
May 2023		5
June 2023		5
July 2023		5
August 2023		5
September 2023	15-10-23 38 Ltrs	4
October 2023		5
November 2023		5
December 2023		5
January 2024		4
February 2024		3
March 2024		3
TOTAL	38 Ltrs	54 Kgs

Annexure -VI

**MONTHWISE WATER CONSUMPTION AND
WASTE WATER GENERATION**

During the year April 2023 - March 2024

Month	Water consumption (in Lts)			Effluent Generation (in Lts)		
	Process	Domestic	Total	Process	Domestic	Total
April 2023	104300	90000	194300	137500	30000	167500
May 2023	143800	93000	236800	137500	31000	168500
June 2023	96900	90000	186900	132000	30000	162000
July 2023	117150	90000	207150	143000	30000	173000
August 2023	137700	93000	230700	132000	31000	163000
September 2023	136400	90000	226400	137500	30000	167500
October 2023	143900	93000	236900	132000	31000	163000
November 2023	107600	90000	197600	137500	30000	167500
December 2023	158000	93000	251000	132000	31000	163000
January 2024	151100	93000	244100	143000	31000	174000
February 2024	81900	87000	168900	137500	29000	166500
March 2024	131700	93000	224700	143000	31000	174000
TOTAL	1510450	1095000	2605450	1644500	365000	2009500

**MONTHWISE
DIESEL & ENERGY CONSUMPTION DETAILS**

During year April 2023 - March 2024

Month	Diesel	Energy
	(Litre)	(KWH)
April 2023	3680	93959
May 2023	4705	107375
June 2023	4550	98298
July 2023	4580	78696
August 2023	4675	106830
September 2023	5400	109286
October 2023	4970	100962
November 2023	2910	82050
December 2023	3970	90496
January 2024	3740	87992
February 2024	1650	71994
March 2024	2400	90748
TOTAL	47230	1118686

Ambient Air Quality Monitoring Report

Annexure-VIII



KKB
MICRO TESTING LABS PVT. LTD.
In Pursuit of Excellence



TC - 6355

Accredited by NABL, ISO 9001:2015 & ISO 45001: 2018 certified Laboratory, Approved by MoEF&CC

TEST REPORT

ULR – TC635524000000983F

Discipline : Chemical

Product Group : Atmospheric Pollution

Sub Group : Ambient Air

Report Reference Number: KMTLPL/23-24/1792/AAQ/8431-8433

Issue Date: 18.03.2024

Issued To: M/s. Dano Vaccines & Biologicals Pvt. Ltd. 575, Sivareddyguda, Ghatkesar, Hyderabad -501301.			Lr. Reference No. & Date NIL		
			Sample Receipt Date 12.03.2024		
			Analysis Starting Date 13.03.2024		
			Analysis Completion Date 14.03.2024		
Sample Details: Ambient Air Quality			Sample condition on Receipt Good		
S.No	Location	Latitude	Longitude	Atmospheric condition	Ambient Temperature
1	Near Security	17.397668	78.516474	Clear Sky	32.3°C
2	Near Production Building	17.397643	78.516457		
3	Near Boiler	17.397626	78.516482		
Tests Requested: Particulate Matter (PM ₁₀ , PM _{2.5}), Sulphur Dioxide & Oxides of Nitrogen					

TEST RESULTS

S. No.	Parameter	UOM	Test Method	NAAQ Standards	Result		
					1	2	3
1	Particulate Matter (PM ₁₀)	µg/m ³	IS 5182 Pt 23: 2006 RA 2022	100	72	68	57
2	Particulate Matter (PM _{2.5})	µg/m ³	In House Validated SOP 11 Issue 02 dated 14.05.2018	60	30.7	29.6	24.5
3	Sulphur Dioxide (SO ₂)	µg/m ³	IS 5182 Pt 2/Sec.1: 2023	80	19	16	13
4	Oxides of Nitrogen (NO _x)	µg/m ³	IS 5182 Pt 6: 2006 RA 2022	80	34	30	27

UOM : Unit of Measurement

Samples are drawn by representative of KMTLPL

Amrutha Nalini
 Verified by
 Amrutha Nalini
 Sr. Chemist

CH. Vijaya Kumar
 Authorized Signatory
 CH. Vijaya Kumar
 Lab Director

* End of the Report *

Page 1 of 1

Note : This report is subject to the Terms & Conditions mentioned Overleaf

Disclaimer: The results are applicable only to the sample tested. Endorsement of the product is neither inferred nor implied.

[Services Offered: Environmental Monitoring, Water, Effluents, Soil, Food & Feed, Ores & Minerals, Oils etc.]
 Address: 2nd Floor, 3-5-244, NFC Main Road, Krishna Nagar Colony, Mouda-Atli, Hyderabad-500 040 (Telangana)
 Phone : + 91 80190 47107, + 91 80190 77107; E-mail : kkb.mtlpl@gmail.com

Treated Effluent Analysis Report

Annexure-IX



KKB
MICRO TESTING LABS PVT. LTD.
In Pursuit of Excellence



Accredited by NABL, ISO 9001:2015 & ISO 45001: 2018 certified Laboratory, Approved by MoEF&CC

TEST REPORT

ULR – TC635524000000987F

Discipline : Chemical

Product Group : Pollution & Environment

Sub Group : Waste Water (Effluents / Sewage)

Report Reference Number: KMTLPL/23-24/1792/EPF/B441

Issue Date: 18.03.2024

Issued To: M/s. Dano Vaccines & Biologicals Pvt. Ltd. 575, Sivareddyguda, Ghatkesar, Hyderabad -501301.	Lr. Reference No. & Date	Nil
	Sample Receipt Date	12.03.2024
	Analysis Starting Date	13.03.2024
	Analysis Completion Date	18.03.2024
Sample Details: Waste Water (ETP Outlet)	Quantity Received	2 L x 1 No. in plastic can and 500 ml x 2 No. in glass bottle
	Sample condition on Receipt	Good
	Source / Location	ETP Outlet
Tests Requested: pH, TDS, TSS, Chlorides, Sulphates, COD, BOD and Oil & Grease		

TEST RESULTS

S. No.	Parameter	UOM	Test Method	Result
1	pH	--	IS 3025 : 2012 Part 11	7.84
2	Total Dissolved Solids	mg/l	IS 3025 : 2023 Part 16	543
3	Total Suspended Solids @ 105° C	mg/l	IS 3025 : 2022 Part 17	12
4	Chlorides as Cl	mg/l	IS 3025 : 1988 Part 32 RA 2019	182
5	Sulphates as SO ₄	mg/l	IS 3025 : 1986 Part 24 RA 2019	130
6	Chemical Oxygen Demand – COD	mg/l	IS 3025 : 2023 Part 58	188
7	Biochemical Oxygen Demand – BOD (3 days @ 27°C)	mg/l	IS 3025 : 2023 Part 44	29
8	Oil & Grease	mg/l	IS 3025 : 2021 Part 39	BDL

UOM : Unit of Measurement; BDL : Below Detection Limit
Detection Limit: Oil & Grease : 0.1 mg/l.

Amrutha Nalini
Verified by
Amrutha Nalini
Sr. Chemist

CH. Vijaya Kumar
Authorized Signatory
CH. Vijaya Kumar
Lab Director

* End of the Report *

Page 1 of 1

Note : This report is subject to the Terms & Conditions mentioned Overleaf

Disclaimer: The results are applicable only to the sample tested. Endorsement of the product is neither inferred nor implied.

[Services Offered: Environmental Monitoring, Water, Effluents, Soil, Food & Feed, Ores & Minerals, Oils etc.]
Address: 2nd Floor, 3-5-244, NFC Main Road, Krishna Nagar Colony, Mouta-A(1), Hyderabad-500 D40 (Telangana)
Phone : + 91 80190 47107, + 91 80190 77107; E-mail : kkb.mtlpl@gmail.com

Noise Monitoring Report

Annexure -X



KKB
MICRO TESTING LABS PVT. LTD.
In Pursuit of Excellence



Accredited by NABL, ISO 9001:2015 & ISO 45001: 2018 certified Laboratory, Approved by MoEF&CC

TEST REPORT

ULR – TC63552400000098SF

Discipline : Chemical

Product Group : Atmospheric Pollution

Sub Group : Ambient Noise (Excluding Vibration)

Report Reference Number: KMTLPL/23-24/1792/NO5/8435-8439

Issue Date: 18.03.2024

Issued To: M/s. Dano Vaccines & Biologicals Pvt. Ltd. 575, Sivareddyguda, Ghatkesar, Hyderabad -501301.	Lr. Reference No. & Date Nil	Sample Receipt Date 12.03.2024
Sample Details: Ambient Noise Level Monitoring (Date of Collection : 12.03.2024 Duration Period: 12:00 Hrs to 13:05 Hrs) (Samples are drawn by representative of KMTLPL) Tests Requested: Ambient Noise Level	Analysis Starting Date	Not Applicable
	Analysis Completion Date	Not Applicable
	Quantity Received	Not Applicable
	Sample condition on receipt	Not Applicable
	Source / Location	As mentioned Below

TEST RESULTS

S. No.	Location / Unit	UOM	Latitude	Longitude	Result
1	Near Security	dB(A)	17.397628	78.516467	53.3
2	Near Production Building	dB(A)	17.397642	78.516434	55.4
3	Near Boiler	dB(A)	17.397636	78.516452	58.5
4	Near DG ON Condition	dB(A)	17.397447	78.516572	67.8
5	Near DG OFF Condition	dB(A)	17.397447	78.516572	53.7

Test Method : IS 9989 : 1981 RA 2020

Noise Level Standards

Area Code	Category of Area	UOM	Limits – Day Time [06:00 Hrs to 22:00 Hrs]	Limits – Night Time [22:00 Hrs to 06:00 Hrs]
A	Industrial Area	dB(A)	< 75	< 70
B	Commercial Area	dB(A)	< 65	< 55
C	Residential Area	dB(A)	< 55	< 45
D	Silence Zone	dB(A)	< 50	< 40

UOM : Unit of Measurement

Amrutha Nalini
 Verified by
 Amrutha Nalini
 Sr. Chemist

CH. Vjaya Kumar
 Authorized Signatory
 CH. Vjaya Kumar
 Lab Director

* End of the Report *

SCHEDULE - A

SL No.	Specific Conditions	Compliance
1	The applicant shall make applications for renewal of Consent (under Water and Air Acts) and Authorization under HWM Rules at least 4 months before the date of expiry of this order, along with prescribed fee under Water and Air Acts for obtaining consent & HW Authorization of the Board.	We have noted and we are applying for CFO renewal application.
2	The industry shall immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions etc.	We have noted and we are applying for CFO renewal application.
3	a) All the fugitive emissions shall be controlled with proper measures. b) The applicant shall also install the equipment such as wind Speed recorder and wind direction recorder.	a) We have taken all necessary Measures to control the fugitive emissions. b) The industry has provided wind sack. We will also install equipment to record wind speed and direction.
4	The applicant shall not change or alter either the quality or the Quantity or the rate of the discharge or the route of discharge and shall not change or alter either the prescribed quality or the rate of emission without the previous written permission of the Board.	We have noted and we are complying with the condition.
5	The applicant shall, not later than 30 days from the date of issue of This consent order, certify in writing to the Board that the applicant has installed or provided an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent. In absence of alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production shall be stopped.	We installed the 500KV DG set for standby power supply.
6	Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and / or violation of standards stipulated in this order or the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident, or other unforeseen act or event, the person-in-charge of the premises, from where such discharge / emission occurs or is apprehended to occur shall forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax / email under intimation to the Collector and District Magistrate.	We have noted and will comply with the condition.

7	In case of such episode discharges / emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge / emission below the limits prescribed in this order.	We will comply with the Condition and will ensure that we will take immediate action to bring down the discharge/ emission below the limits prescribed in this order.
8	A good housekeeping shall be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers and drains Shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way into storm drains or open areas.	We are regularly maintaining the good housekeeping and all the wash water is admitted into the effluent collection system only.
9	a) The industry shall carryout analysis of wastewater discharges or emissions through chimneys, for the parameters mentioned in Schedule B of this order at regular intervals. b) The industry shall maintain following records to the Board, whenever required. 1. Analysis reports of wastewater/ emissions. 2. Logbook for operation of pollution control systems. 3. Inspection book	a) We are carrying out analysis of wastewater discharges or emissions through chimneys for the parameters mentioned Schedule B at regular intervals. b) We are maintaining the records of the following as: 1. Analysis reports of wastewater/ emissions. 2. Logbook for operation of pollution control systems. 3. Inspection book
10	The applicant shall set up THREE Ambient Air Quality Monitoring Stations for continuous recording of relevant critical parameters mentioned in Schedule - B as per the CPCB guidelines and submit monthly reports	Regular Monitoring being done by MoEF approved Lab and the values are within the prescribed limits.
11	Separate power connection with energy meter shall be provided for the Pollution Control Equipment and record of power consumption and chemicals consumption for the operation of pollution control equipment shall be maintained separately.	We have provided the separate power connection with energy meters as per the condition and we are recording the consumption record of power and chemicals for the operation of pollution control equipment.
12	The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No. 14 of E (P) Rules, 1986 & its amendments thereof.	We are submitting the Form - V (Environment statement) regularly to the Board. We will submit Form V for the financial year 2023-24 on 30-09-2024.
13	The applicant shall comply with the directives/orders issued by the Board in this consent order and at all subsequent times without any negligence on his part. The applicant shall be liable for such legal action against him as per provisions of the Law/Act in case if non- compliance of any order/directive issued at any time and/or Violation of the terms and conditions of this consent order.	We have noted the condition and will ensure that we will comply with all directions of the Board.

14	The applicant shall furnish to the visiting officer and / or the Board any information regarding the construction, installation or operation of the effluent treatment system / air pollution control equipment and such other particulars as may be pertinent for preventing and Controlling pollution.	We have noted the condition.
15	The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability	We have noted and will comply with the condition.
16	All the rules & regulations notified by Ministry of Environmental and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes Shall be followed.	We have noted and complying with the condition.
17	All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 shall be followed.	We have noted and having the Public Liability insurance copy dt:04-11-2023 and valid up to dt 03-11-2024 NATIONAL INSURANCE COMPANY Policy No. 551200492310000091
18	The occupier shall educate the workers and nearby public of Possible accidents and remedial measures.	We are complying with the condition
19	For any accident or spillage of hazardous wastes causing damage to the Environment the occupier or the transporter as the case Shall be held responsible.	We have noted and complying with the condition.
20	In case of closure of industry, the Un-used/not consumed raw materials falling under the category of Hazardous Chemicals and mentioned in Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment Rules, 2003 shall be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident, In case the above hazardous chemicals have lost their properties originally acquired, then they shall be treated as Hazardous Waste and they should be disposed off only to the authorized agencies of TSPCB in a safe manner.	We have noted and will complying with the condition
21	The occupier shall prepare / update an emergency preparedness plan for safe handling of hazardous waste from time to time and submit the same to TSPCB, Emergency preparedness plan must be Implemented immediately whenever there is fire, explosion or release of hazardous waste or hazardous waste constituents, which could endanger to human health or environment.	We are implementing the suggestions as per Emergency preparedness plan (Onsite Emergency Plan) given by the safety experts.
22	Packaging labeling and transportation of Hazardous Wastes shall be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and	Packaging labeling and transportation of Hazardous Wastes are in accordance with the provisions of the rules issued by the

	other guidelines issued from time to time. The packaging and labeling shall be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.	Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling are based on the composition and hazardous constituent of the waste and all Hazardous Waste containers are providing with a general label.
23	The driver who transports Hazardous Waste should be well Acquainted about the procedure to be followed in case of an emergency during transit. The transporter shall carry a Transport Emergency (TREM) card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.	The driver who is transporting the Hazardous Waste is well Acquainted about the procedure to be followed in case of an emergency during transit. He shall carry a Transport Emergency (TREM) card (as given in the guidelines for management and handling of hazardous wastes) duly filled.
24	Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes should be thoroughly detoxified before selling to agencies authorized by TSPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste Containers / container Liners should be maintained in the following way. i. Number of containers received. ii Date and method of detoxification iii Name of agencies to whom containers were sold with quantities, iv. Transportation particulars.	Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes are detoxified before selling to agencies authorized by TSPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste Containers / container Liners are maintained in the following way. i. Number of containers received. ii Date and method of detoxification iii Name of agencies to whom containers were sold with quantities, iv. Transportation particulars.
25	No Hazardous Wastes shall be mixed with any other waste or shall be discharged to a common, other internal, external sewerage or other drainage system without prior approval of TSPCB.	We are generating only Waste Oil and ETP Sludge as Hazardous waste which will be sent to TSPCB Authorized recyclers and Used as Manure respectively. No hazardous Waste is mixed with any other or discharged to sewerage.
26	If HDPE bags are used for storing Hazardous Wastes, it should be Ensured that they are perfectly sealed mechanically or double hot sealed. If MS / HDPE bags or drums are used for Hazardous Wastes, these drums / bags should be ensured that they are perfectly sealed.	We have noted and ensure that the packing will be perfectly sealed.
27	The person authorized shall not rent, lend, sell, transfer their Industrial premises without obtaining prior permission of State Pollution Control Board.	We have noted and will comply with the condition.
28	Any Unauthorized change in personal, equipment and working condition as mentioned in the application by the person authorized shall constitute a breach of this authorization.	We have noted the condition.
29	The industry shall comply with the provisions of Batteries (Management and Handling) Rules, 2001.	We have noted the condition.

30	<p>The applicant shall put up two black boards of size 6 ft by 4 ft. at The main entrance to their plant. One board shall contain the specific CFE and CFO conditions, in sufficiently large font size so that it can be read easily from a distance of 10 ft to a normal eye, and other board shall carry, again in sufficiently large font size so as to be able to read from a distance of 10 ft, the latest Water, Air, Noise and solid waste monitoring data as well as the maximum Vulnerable zone.</p>	We already complied with the condition.
31	<p>The applicant shall exhibit the Consent & HW Authorization order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.</p>	We already complied with the condition.
32	<p>Not with standing anything contained; in this conditional letter or consent, the Board hereby reserves to it the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and its amendments thereof and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and its amendments thereof to review any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.</p>	We have noted the condition.
33	<p>The authorization issued under Hazardous Waste (Management, Handling & Trans boundary Movement) Rules, 2008, shall comply with the provision of the Environment (Protection) act, 1986.</p>	We have noted the condition.
34	<p>Any person aggrieved by an order made by the State Board under section 25, section 26,section 27 of Water Act, 1974 or section 21 of Air Act,1981 may within thirty days from the date on which the order is communicated to him , prefer an appeal as per Telangana state Water rules ,1976 and Air Rules 1982, to such authority (Here in after referred to as the Appellate Authority) constituted under Section 28 of the Water (prevention and control of pollution) Act, 1974 and section 31 of the Air (prevention and control of pollution) Act,1981.</p>	We have noted the condition.

SCHEDULE - B

S.No.	Specific Condition	Compliance																											
1	<p>The industry shall take steps to reduce water consumption to the extent possible and consumption shall NOT exceed the quantities mentioned below.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">S.No.</th> <th style="text-align: center;">Purpose</th> <th style="text-align: center;">Total Quantity (KLD)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1.</td> <td>Process</td> <td style="text-align: center;">6.0 KLD</td> </tr> <tr> <td style="text-align: center;">2.</td> <td>Washings</td> <td style="text-align: center;">8.0 KLD</td> </tr> <tr> <td style="text-align: center;">3.</td> <td>Boiler Feed</td> <td style="text-align: center;">21.0 KLD</td> </tr> <tr> <td style="text-align: center;">4.</td> <td>Cooling make up</td> <td style="text-align: center;">25.0 KLD</td> </tr> <tr> <td style="text-align: center;">5.</td> <td>Canteen</td> <td style="text-align: center;">6.0 KLD</td> </tr> <tr> <td style="text-align: center;">6.</td> <td>Domestic</td> <td style="text-align: center;">6.0 KLD</td> </tr> <tr> <td style="text-align: center;">7.</td> <td>Domestic from Quarters</td> <td style="text-align: center;">20.0 KLD</td> </tr> <tr> <td></td> <td style="text-align: center;">Total</td> <td style="text-align: center;">92.0 KLD</td> </tr> </tbody> </table>	S.No.	Purpose	Total Quantity (KLD)	1.	Process	6.0 KLD	2.	Washings	8.0 KLD	3.	Boiler Feed	21.0 KLD	4.	Cooling make up	25.0 KLD	5.	Canteen	6.0 KLD	6.	Domestic	6.0 KLD	7.	Domestic from Quarters	20.0 KLD		Total	92.0 KLD	<p>Necessary steps are taken to ensure the reduction of water consumption within the factory premises.</p>
S.No.	Purpose	Total Quantity (KLD)																											
1.	Process	6.0 KLD																											
2.	Washings	8.0 KLD																											
3.	Boiler Feed	21.0 KLD																											
4.	Cooling make up	25.0 KLD																											
5.	Canteen	6.0 KLD																											
6.	Domestic	6.0 KLD																											
7.	Domestic from Quarters	20.0 KLD																											
	Total	92.0 KLD																											
2	The industry shall remit water cess as per the assessment orders as and when issued by Board.	<p>Water cess is being remitted by the industry as and when issued by the Board</p>																											
3	<p>The emissions shall not contain constituents in excess of the prescribed limits mentioned below. (115 mg/Nm³).</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Chimney No.</th> <th style="text-align: center;">Parameter</th> <th style="text-align: center;">Emission Standards (mg/Nm³)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1 to 4</td> <td style="text-align: center;">SPM</td> <td style="text-align: center;">115</td> </tr> </tbody> </table>	Chimney No.	Parameter	Emission Standards (mg/Nm ³)	1 to 4	SPM	115	<p>We have engaged MoEF approved laboratories (KKB Micro Testing Labs Pvt. Ltd.) for regular monitoring. The Emission standards (mg/Nm³) are monitored every month and the results are within the specified limits set by TSPCB standards.</p>																					
Chimney No.	Parameter	Emission Standards (mg/Nm ³)																											
1 to 4	SPM	115																											
4	<p>The industry shall comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG set more than 800 KW shall comply with emission limits as per the Notification G.S.R.489(E), dated 09.07.2002 at serial No. 96, under the Environmental (Protection) Act, 1986.</p>	<p>The Emission standards (mg/Nm³) are monitored every month by KKB Micro Testing Labs Pvt. Ltd. and the results are below the specified limits set by TSPCB standards.</p>																											
5	<p>The industry should comply with the National ambient air quality standards as per MoEF, GoI notification dated 18.11.2009 along with the premises of the factory as prescribed below.</p>	<p>Ambient air quality standards are monitored by KKB Micro Testing Labs Pvt. Ltd. every month and the results are well within the limits as standards set by TSPCB.</p>																											

ANNEXURE - XI

	S.No.	Parameters	Standards in $\mu\text{g}/\text{m}^3$	
	1	PM ₁₀	100	
	2	PM _{2.5}	60	
	3	SO ₂	80	
	4	NO _x	80	
6	The industry shall manufacture only consented products and shall produce within the consented capacities. Under no circumstances, the industry shall manufacture any un-consented products without obtaining CFE and CFO of the Board.			Manufacture of consented products is carried out within the facility and the production details are submitted in FORM - IV every year to the Board office. The production of un-consented products is not encouraged in the factory.
7	The industry shall regularly operate ETP for effluents and after treatment, the treated wastewater shall be utilized for on land for gardening within the premises duly complying with the standards stipulated by the Board			Effluent treatment plant is operated daily in the facility and the treated waste water is utilized for on land for gardening within the premises complying to the standards stipulated by the Board.
8	The Industry shall provide suitable air pollution control equipment (APCE) to Diesel fired Incinerator of capacity 2 Kgs / Hr and regularly operate the air pollution control equipment to meet the prescribed standards.			Air pollution control equipment (APCE) is provided to the Diesel fired Incinerator (2 Kgs / Hr) and is regularly operated to meet the prescribed standards.
9	The industry shall install a separate energy meter for the Effluent treatment plant and APCE and maintain log registers to record the energy meter readings pertaining to the operation of ETP and APCE.			Separate Energy meter is installed and the readings are recorded in the log book for ETP plant
10	The Industry shall not discharge any waste water outside the factory premises.			Waste water is treated in the ETP plant and used for gardening within the factory premises. Waste water is not discharged outside the factory premises.
11	The Industry should not dispose any solid waste outside the premises.			Solid waste generated from the ETP is used as manure and not disposed outside the premises.
12	The industry shall not cause any air pollution / dust nuisance to the surrounding environment.			Noise levels are being monitored by the external agency (KKB Micro testing Labs) once in a month and the results are being closely monitored and all the results are well within the predetermined specifications.
13	The Industry shall develop 33% of the total area as thick green belt all along the boundary of the unit and also in the vacant places with all growing trees with wide leaf area			Trees are planted all along the boundaries of the facility and 33% of the total area is occupied with thick green belt.
14	The Industry should maintain the following records and officials during the inspection.			the same should be made available to the Board
	a) Daily Production details, RG-I records and Central excise returns			Daily production records are maintained and monthly production records are submitted every year to the Board Office
	b) Quantity of effluents generated, treated in ETP and utilised for Gardening			ETP log book maintained within the organisation
	c) Log books for Pollution control system			Log book for pollution control system is

ANNEXURE - XI

		maintained
	d) Daily solid waste generated and disposed.	Daily solid waste generated record is maintained within the facility
15	The Industry shall submit the Environmental statement in Form V before 30th September every year as per Rule No. 14 of Environmental (Protection) Act, 1986.	Environmental statement is submitted to the Board office in Form V by the 30th of september every year.
16	The following rules and regulations notified by the MoE&F, GoI shall be implemented.	
	a) Solid Waste Management rules, 2016.	Not Applicable
	b) Construction and Demolition Waste Management Rules, 2016.	Not Applicable
	c) Hazardous and other waste (Management and Transboundary Movement) Rules 2016 and its amendments	Maintained in coordination with M/s Supreme Lubricants Pvt. Ltd.
	d) Batteries Amendment Rules, 2010 and its amendments	Not Applicable
	e) E-Waste (Management) Rules, 2016	Not Applicable
	f) Bio-Medical Waste Management Rules, 2016 & its amendments	Maintained in coordination with M/s Sattva Enviro systems.
	g) Plastic waste Management rules, 2016 & its amendments	Maintained in coordination with M/s Sattva Enviro systems.
17	The Industry shall take necessary measures to control fugitive emissions	We have taken all necessary measures to control the fugitive emissions.
18	The Industry shall take all precautionary and safety measures during process operation.	Usage of Personal Protective Equipments is encouraged during the process operation to prevent unnecessary injuries in the workplace. Safety training is also provided to all the concerned users by the trained officers on yearly basis.
19	The Industry shall comply with all the directions issued by the Board from time to time.	We shall comply the directions issued from the board from time to time.
20	Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control acts.	The data submitted to the Board office is true and accurate to the best of knowledge.
21	The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.	We have noted and comply with the condition.
22	This order is issued to the industry without prejudice to the action taken by the Task Force of the Board.	We have noted the condition.

SCHEDULE - C

S.No.	Specific Condition	Compliance
1	The industry shall give top priority for waste minimization and cleaner production practices.	Good Manufacturing practices are followed inside the production premises. The waste generated during the process is transferred to the scrap yard, which in turn is disposed to the Authorized Vendor.
2	The industry shall not store hazardous waste for more than 90 days as per the Hazardous & other wastes (Management and Transboundary Movement) Rules, 2016.	Hazardous waste (Used oil) is disposed to Authorized reprocessor / recycler (M/s SUPREME LUBRICANTS PVT. LTD.) on quarterly basis with proper labeling and packing meeting all conditions for transport by road.
3	The Industry shall not sell the used empty drums / barrels / liners / bags / Bottles etc. to outside parties & vendors for reuse, which is resorting in illegal dumping of Hazardous waste and shall dispose the same directly to authorized recyclers only.	There is no usage of Barrels / drums / bags / bottles / liners within the factory premises. However, some plastic drums are used to store the Biomedical waste and these drums are sent directly to the authorized disposal agency (M/s Sattva Enviro Systems)
4	The industry shall ensure proper labelling of Hazardous waste / other waste containers with particulars of industry & type of waste along with the characteristics, while storage & transporting the waste to Recyclers / TSDF/ Cement Industries.	Hazardous waste (Used / Waste oil) is labeled, properly packed in closed containers and transported in vehicle to the authorized recycler / reprocessor.
5	The industry shall store Used / Waste oil and used Lead Acid Batteries in a secured way in their premises till its disposal.	Dedicated area is available for storage of Used / Waste oil within the factory premises. Only Authorized personnel have access to enter into these areas.
6	The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors / Recyclers.	Waste oil is being transferred to the authorized Reprocessor / recycler (M/s Supreme Lubricants Pvt. Ltd.) with proper labeling and packing in all conditions for proper transport by road.

Dano Environmental Statement

ANNEXURE - XII

7	The industry shall dispose Used Lead acid batteries to the manufacturers / dealers on buyback basis.	There is no usage of lead acid batteries within the factory premises.
8	The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.	Necessary steps have been taken to prevent oil spillages inside the factory premises. It is being transported to the authorized reprocessor in closed containers with proper labeling and packing.
9	The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board office and concerned Regional office.	The industry had a practice of maintaining 6 copy manifest system of waste generated and copy is being submitted to Board office and concerned Regional office every year.
10	The industry shall maintain good house keeping & maintain proper records for Hazardous Wastes stated in Authorization.	Good House Keeping is being maintained within the organisation and proper records are maintained for the Hazardous waste stated.
11	The industry shall maintain proper records for Hazardous Waste stated in Authorization in FORM - 3 and file annual returns in FORM - 4 Rules 6(5), 13(8), 16(6) and 20(2) as per Hazardous & other waste (Management, Transboundary Movement) Rules, 2016.	We are complying with the condition.
12	The industry shall submit the conditions wise compliance report of the conditions stipulated in Schedule B & C of this order on half yearly basis to Board office, Hyderabad and concerned Regional Office.	Here after, Compliance report of the conditions stipulated in Schedule B & C of this order is being submitted to the Board office on half yearly basis.
13	The industry shall dispose the e-waste to authorized recyclers / re-processors only.	e - Waste is not generated within the factory premises.